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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,918	10/24/2003	Frank Grosveld	CARP0015-101	9062

34132 7590 02/27/2006

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EXAMINER

SINGH, ANOOP KUMAR

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/692,918	Applicant(s) GROSVELD, FRANK	
	Examiner Anoop Singh	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

1. Claims 1-32 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-16, drawn to a method for the production of a VHH single heavy chain and camelised VH heavy chain antibody in a mammal, classified in class 436, subclass 547.
 - II. Claims 17-19, drawn to a VHH single heavy chain antibody, classified in class 424, subclass 130.1.
 - III. Claims 20-24, drawn to a camelised VH single heavy chain antibody, classified in class 424, subclass 130.1.
 - IV. Claims 25-27, drawn to a vector comprising a VHH heavy chain or camelised VH heavy chain locus and cell transformed by said vector, classified in class 424, subclass 93.2.
 - V. Claims 28-31, drawn to a transgenic mammal expressing a heterologous VHH heavy chain locus or camelised VH heavy chain locus and a method of producing single chain antibodies by immunizing a transgenic mammal, classified in class 800, subclass 8.
 - VI. Claim 32, drawn to a method of using a single heavy chain for the prophylaxis and or treatment of disease, classified in class 424, subclass 184.1.
3. The inventions of groups I and VI are patentably distinct each from other because they are drawn to methods that use material compositions that have distinct structure, function and utility. The invention of method group I requires producing an antibody, by using a construct which have distinct physical and chemical structure, compared to invention of method group VI that require administering or immunizing the subject for the treatment of a disease. Additionally, the method step of producing an antibody would be distinct and different from those of treatment method. Thus,

searching for steps used in treatment method of group V will not be coextensive with method step of group I in the patent and non-patent literature.

The Inventions of groups II-V are patentably distinct each from other because they are drawn to compositions that have distinct structure, function and mode of utilities. For example, the invention of group II requires a VHH single heavy chain antibody, while inventions of group III requires a camelised VH single heavy chain antibody. In contrast, compositions of group IV require a transformed cell that is distinct and different from composition of group V directed to a transgenic animal. They all have distinct physical structure and function. The utility of an antibody will be distinct and different as compare to a transformed cell or a transgenic animal. In addition, the inventions of groups III-V have a separate status in the art as shown by their different classifications. Thus, searches for compositions used in groups II-V will not be coextensive in the patent and non-patent literature.

The composition of the groups II-V is patentably distinct each from the methods of groups I and VI because methods cannot be used to produce the compositions. Alternatively, the compositions may not be used in methods or will be used in more than one method.

Therefore, the inventions of groups I-VI are patentably distinct each from other and will require separate and non-coextensive searches in the patent and non-patent literature.

4. A search and examination of more than one invention as defined above would unduly burden the office. Each of the invention requires a different search of the art and concerns separate consideration of patentability. For example, the subject matter of many of the inventions is not largely co extensive as the inventions are related to distinct methods. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anoop Singh whose telephone number is (571) 272-3306. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272- 0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER

Anoop Singh, Ph.D.
Examiner, AU 1632